



December 2016

Summary of the Risk Assessment and Risk Management Plan

for

Licence Application No. DIR 143

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for the intentional, commercial scale release of insect resistant and herbicide tolerant genetically modified (GM) cotton in Australia. A Risk Assessment and Risk Management Plan (RARMP) for this application was prepared by the Regulator in accordance with requirements of the *Gene Technology Act 2000* (the Act) and corresponding state and territory legislation, and finalised following consultation with a wide range of experts, agencies and authorities, and the public. The RARMP concludes that this commercial release poses negligible risks to human health and safety and the environment and no specific risk treatment measures have been imposed. However, general licence conditions have been imposed to ensure that there is ongoing oversight of the release.

The application

Application number:	DIR 143
Applicant:	Bayer CropScience Pty Ltd (Bayer)
Project Title:	Commercial release of cotton genetically modified for insect resistance and herbicide tolerance (GlyTol [®] (BCS-GH002-5) and GlyTol TwinLink Plus [®] (BCS-GH002-5 x BCS-GH004-7 x BCS-GH005-8 x SYN-IR102-7)) ¹
Parent organism:	Cotton (<i>Gossypium hirsutum</i> L.)
Introduced gene and modified trait:	Three insect resistance genes <ul style="list-style-type: none">• <i>Cry1Ab</i> gene from <i>Bacillus thuringiensis</i> (Bt)• <i>Cry2Ae</i> gene from Bt• <i>Vip3Aa19</i> gene from Bt Two herbicide tolerance genes <ul style="list-style-type: none">• <i>bar</i> gene from <i>Streptomyces hygroscopicus</i> for glufosinate tolerance• <i>2mepsps</i> gene from <i>Zea mays</i> (maize) for glyphosate tolerance One selectable marker gene <ul style="list-style-type: none">• <i>aph4</i> from <i>Escherichia coli</i> for resistance to hygromycin B

¹ The title of the licence application submitted by Bayer is “Commercial release of GlyTol[®] cotton and GlyTol TwinLink Plus[®] cotton (*Gossypium Hirsutum* L.) for use in the Australian cropping system”.

Proposed locations:	Australia-wide
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This commercial release follows field trial work conducted under licence DIR 133.

Risk assessment

The risk assessment concludes that risks to the health and safety of people, or the environment, from the proposed release, either in the short or long term, are negligible.

The risk assessment process considers how the genetic modification and activities conducted with the GMO might lead to harm to people or the environment. Risks were characterised in relation to both the seriousness and likelihood of harm, taking into account information in the application, relevant previous approvals, current scientific knowledge and advice received from a wide range of experts, agencies and authorities consulted on the preparation of the RARMP. Both the short and long term impacts were considered.

Credible pathways to potential harm that were considered included: toxic and allergenic properties of the GM cotton; potential for increased weediness of the GM cotton relative to unmodified plants; and vertical transfer of the introduced genetic material to other sexually compatible plants.

The principal reasons for the conclusion of negligible risks are: the introduced proteins are not considered toxic or allergenic to people or toxic to vertebrates and most invertebrates; toxicity of the introduced insect-resistance proteins is limited to certain insects, including major pests of cotton; the GM cottons and other GM cotton lines containing the introduced genes have previously been assessed and authorised for field trial and/or commercial release in Australia and have a history of safe use overseas; the introduced genes and proteins are widespread in the environment; the GM cottons and their progeny can be controlled using integrated weed management; the GM cottons are susceptible to the biotic or abiotic stresses that normally restrict the geographic range and persistence of cotton; and the limited capacity of the GM cotton to spread and persist in undisturbed natural habitats. In addition, food made from the GM cottons has been approved by Food Standards Australia New Zealand as safe for human consumption.

Risk management

The risk management plan describes measures to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan is given effect through licence conditions.

As the level of risk has been assessed as negligible, specific risk treatment is not required. However, the Regulator has imposed licence conditions to ensure that there is ongoing oversight of the release and to allow the collection of information to verify the findings of the RARMP. The licence also contains a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements, which include an obligation to report any unintended effects.